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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,649	03/30/2006	Guoqing Cao	X16501	5478
25885 7590 11/10/2009 ELI LILLY & COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288				
EXAMINER COLEMAN, BRENDA LIBBY				
ART UNIT		PAPER NUMBER		
1624				
NOTIFICATION DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

### Office Action Summary

**Application No.**

10/574,649

**Applicant(s)**

CAO ET AL.

**Examiner**

Brenda L. Coleman

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 8, 9, 12, 14, 16, 18, 20, 22 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 is/are allowed.
- 6) ☒ Claim(s) 5 is/are rejected.
- 7) ☒ Claim(s) 1-4, 8, 9, 14, 16, 18, 20, 22 and 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims 1-5, 8, 9, 12, 14, 16, 18, 20, 22 and 26 are pending in the application.

This action is in response to applicants' amendment filed July 10, 2009. Claims 1-5, 8 and 12 have been amended and claim 15 has been canceled.

#### ***Response to Amendment***

Applicant's amendments filed July 10, 2009 have been fully considered with the following effect:

1. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 2) in the last office action, which is hereby **withdrawn**.
2. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 3a), b), c), d), e), f), g), h), j), k), l), m), n) and o) in the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled paragraph 3i) in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.
  - i) The applicants' state that the applicant has amended claim 5 to recite the term C<sub>1</sub>-C<sub>6</sub>-alkycycloalkyl. However, the rejection was that it is not know what is meant by "alky" in the term recently amended to be C<sub>1</sub>-C<sub>6</sub>alkycycloalkyl. It is believed that the applicants' intended C<sub>1</sub>-C<sub>6</sub>alkylcycloalkyl.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

In view of the amendment dated July 10, 2009, the following new grounds of objection apply:

***Claim Objections***

3. Claims 1, 3, 5 and 20 are objected to because of the following informalities:

a. Claim 1 is objected to for multiple occurrences of missing spaces created by the deletions in previous amendments as set forth below (emphasis added):

R<sup>1</sup> is selected from a group consisting of C<sub>1</sub>-C<sub>6</sub> alkyl, aryl, C<sub>2</sub>-C<sub>6</sub> alkenyl, C<sub>1</sub>-C<sub>6</sub> alkylheterocyclic, C<sub>3</sub>-C<sub>8</sub> cycloalkyl, C<sub>1</sub>-C<sub>6</sub> alkylcycloalkyl; C<sub>1</sub>-C<sub>6</sub> alkylaryl, **heterocyclyl, C<sub>1</sub>-C<sub>6</sub> alkoxy**, aryloxy, OC<sub>1</sub>-C<sub>6</sub> haloalkyl, -OC<sub>3</sub>-C<sub>8</sub> cycloalkyl, -OC<sub>1</sub>-C<sub>6</sub> alkylcycloalkyl, -NR<sub>7</sub>R<sub>8</sub>, -OC<sub>1</sub>-C<sub>6</sub> alkylaryl, -O-heterocyclic, and **-OC<sub>1</sub>-C<sub>6</sub> alkylheterocyclic; and** wherein each of cycloalkyl, aryl and heterocyclic group is optionally substituted with 1 to 3 groups independently selected from oxo, halo, **C<sub>1</sub>-C<sub>6</sub> alkyl, C<sub>1</sub>-C<sub>6</sub> alkoxy, C<sub>1</sub>-C<sub>6</sub> haloalkyl, CONR<sup>11</sup>R<sup>12</sup>**, , C<sub>0</sub>-C<sub>3</sub> alkylNR<sup>11</sup>R<sup>12</sup>, C<sub>0</sub>-C<sub>6</sub> alkylCOOR<sup>11</sup>, **cyano, and** phenyl;

b. Claim 1 is objected to for an extra comma created by the deletions in previous amendments as set forth below (emphasis added):

R<sup>1</sup> is selected from a group consisting of C<sub>1</sub>-C<sub>6</sub> alkyl, aryl, C<sub>2</sub>-C<sub>6</sub> alkenyl, C<sub>1</sub>-C<sub>6</sub> alkylheterocyclic, C<sub>3</sub>-C<sub>8</sub> cycloalkyl, C<sub>1</sub>-C<sub>6</sub> alkylcycloalkyl; C<sub>1</sub>-C<sub>6</sub> alkylaryl, heterocyclyl, C<sub>1</sub>-C<sub>6</sub> alkoxy, aryloxy, OC<sub>1</sub>-C<sub>6</sub> haloalkyl, -OC<sub>3</sub>-C<sub>8</sub> cycloalkyl, -OC<sub>1</sub>-C<sub>6</sub>

alkylcycloalkyl,  $-NR_7R_8$ ,  $-OC_1-C_6$  alkylaryl,  $-O$ -heterocyclic, and  $-OC_1-C_6$  alkylheterocyclic; and wherein each of cycloalkyl, aryl and heterocyclic group is optionally substituted with 1 to 3 groups independently selected from oxo, halo,  $C_1-C_6$  alkyl,  $C_1-C_6$  alkoxy,  $C_1-C_6$  haloalkyl,  $CONR^{11}R^{12}$ ,  $C_0-C_3$  alkyl $NR^{11}R^{12}$ ,  $C_0-C_6$  alkyl $COOR^{11}$ , cyano, and phenyl;

c. Claim 1 is objected to for missing a space created by the deletions in previous amendments as set forth below (emphasis added):

each  $R^7$  is independently selected from a group consisting of hydrogen,  $C_1-C_6$  alkyl,  $O$   $C_1-C_6$  alkyl,  $C_1-C_6$  haloalkyl,  $-C_3-C_8$  cycloalkyl, heterocyclic, and aryl, wherein each of alkyl, is optionally substituted with 1 to 3 groups independently selected **from  $C_1-C_6$  alkoxy**,  $SO_2R^{11}$ , and  $NR^{11}R^{12}$ ;

d. Claim 1 is objected to for containing a space created by a previous amendments as set forth below (emphasis added):

each  $R^7$  is independently selected from a group consisting of hydrogen,  $C_1-C_6$  alkyl,  **$O$   $C_1-C_6$  alkyl**,  $C_1-C_6$  haloalkyl,  $-C_3-C_8$  cycloalkyl, heterocyclic, and aryl, wherein each of alkyl, is optionally substituted with 1 to 3 groups independently selected from  $C_1-C_6$  alkoxy,  $SO_2R^{11}$ , and  $NR^{11}R^{12}$ ;

e. Claim 3 is objected to for containing a comma at the end of the claim following the period.

f. Claim 5 is objected to for a missing space created by the deletions in previous amendments as set forth below (emphasis added):

**Y** is a bond; and  $R^1$  is alkylaryl, alkylheterocyclic,  $C_1$ - $C_6$  alkylcycloalkyl, wherein the aryl, cycloalkyl and heterocyclic groups are each optionally substituted with 1, 2 or 3 groups independently selected from oxo, -COOH,  $C_1$ - $C_6$  alkyl, and  $C_1$ - $C_6$  alkoxy.

g. Claim 20 is objected to for a missing space created by the deletions in previous amendments as set forth below (emphasis added):

A method of treating pathological sequelae due to low levels of plasma HDL-cholesterol in a mammal comprising administering a pharmaceutically effective amount of a compound of claim **1** or a pharmaceutically acceptable salt, thereof, to a patient in need thereof.

Appropriate correction is required.

4. Claims 2, 4, 8, 9, 14, 16, 18, 22 and 26 are objected to as being dependent upon an objected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Allowable Subject Matter***

5. Claim 12 is allowed. None of the prior art of record or a search in the pertinent art area teaches the 2,3,4,5-tetrahydro-benzo[b]azepine compounds as claimed herein.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 1624

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/  
Primary Examiner, Art Unit 1624